TESTIMONY OF ELLIOTT J. MILLENSON
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Good afternoon. I'm Elliott Millenson. I was founder and CEO of Direct Access Diagnostics, the J&J company which developed Confide, the nation's first home AIDS test. I no longer have any financial interest in AIDS testing. But, I do have an interest in public health. I'm here to offer some history on home AIDS testing, a perspective on how FDA's actions have been perceived by industry – the folks who must commit the resources to bring a home test to market - and some thoughts on where to go from here.

I'm a businessperson – but I worked with the U.S. Public Health Service in the 1970s, helping educate Americans about the health consequences of smoking. I've seen firsthand what those in public health face. Strong science sometimes meets stronger politics. When I had the idea for a home AIDS test, I thought of developing a rapid test, since the technology was available. But, it was clear FDA would not approve such a test, so we developed a blood collection kit instead and sought FDA approval. We expected after approval, we would quickly transition to a rapid home AIDS test, which we always knew had much broader appeal.

But, even getting Confide approved turned into a nine year battle. It started with our 1987 application, to which FDA responded by placing a ban on all home AIDS tests. FDA announced in March 1988 they would only consider AIDS test applications "for professional use only in a health care environment".

Industry believed FDA's ban was politically motivated. FDA was pressured by AIDS activists who feared the social consequences of making AIDS tests too easily accessible, and

clinics who feared the financial consequences– reduced government funding if home AIDS testing caught on. Opponents had lobbied aggressively against home AIDS testing at all levels of government, with particular focus on FDA.

Opponents conjured up the scare tactic that face-to-face counseling was essential to prevent suicides, a claim with no scientific basis. In fact, for well over a decade studies have revealed the overwhelming majority of people getting tested for AIDS haven't received counseling anyway.

It took two lawsuits from my company just to get FDA to consider our application. Finally, in 1994 FDA brought Confide before its Advisory Committee, which expressed support. But, in a subsequent private meeting documented in a smoking-gun memo aired by CBS News, CDC opposed Confide, arguing approval could lead to "a sudden increase in referrals to already overburdened health clinics." Two more years passed - about 80,000 more Americans became infected - before FDA finally approved Confide in 1996, nine years after FDA initially refused our application.

That's all history now. But, past actions affect future decisions. AIDS is an incurable sexually transmitted disease – which has already killed half a million Americans. Every day, over 100 more Americans become infected with HIV – most from sex with an infected person. That's a wake up call: some people don't abstain, aren't faithful, and won't use condoms. Actual use data reveal a 10% failure rate for condoms. That's particularly worrisome, since an alarming number of people who know they're infected with HIV don't tell their partners. Encouraging people to know not just their HIV status but that of their partner as well could save many lives and reduce much suffering.

The only truly safe sex is sex between two uninfected partners. We teach our children to put condoms on cucumbers. We need to teach our children the importance of AIDS testing. In our sexually active society, testing must be accessible in many places - especially the home - because the majority of people are reluctant to go to a doctor or clinic for an AIDS test.

A rapid home AIDS test could quadruple the number of Americans getting tested according to CDC data. It's a good sign that a company presented here today. But, FDA needs to encourage many companies to develop and market home AIDS tests. Competition means less expensive, faster, more reliable, and more user-friendly home AIDS tests will be developed – quickly. Companies skilled in reaching consumers will educate Americans about the benefits of AIDS testing, and responsibly market their tests through a broad range of distribution channels, including, no doubt, public clinics who can give the test away to those with limited resources.

But, senior executives at major health care companies believe FDA has had a strong bias against home AIDS testing for two decades. America's most innovative companies will be slow to commit their R&D dollars to home AIDS testing– unless it is clear FDA's longstanding opposition has truly softened. For the good of all Americans, I urge you – the Advisors in this room –recommend FDA send a clear, credible, decisive message to industry that FDA is not just accepting applications, it's aggressively encouraging them. The health of our great nation depends on your courage and conviction. Thank you.